FLUTAMIDE CAPSULES USP

DESCRIPTION
Flutamide capsules contain flutamide, an androgen receptor antagonist, an active systemic antiandrogen having a chemical name, C11H11F3N2O3. Flutamide is a white to yellow powder with a molecular weight of 278.22 and the following structural formula:

C11H11F3N2O3

Each capsule contains 125 mg flutamide. The compound is a white to yellow powder with a molecular weight of 278.22 and the following structural formula:

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INDICATIONS AND USAGE
Flutamide has been demonstrated to slow the growth of metastatic prostate cancer at the castrate level. This can be accomplished in patients who have not responded adequately to previous hormone therapy or in those patients who have documented progression despite hormonal therapy. Low serum testosterone levels are present in all patients with hormone refractory prostatic carcinoma. Flutamide, in combination with orchidectomy or with goserelin acetate (3.6 mg depot) prior to and during radiation was associated with a significantly lower rate of disease progression than radiation alone.

Smaller studies have failed to show a statistically significant advantage for flutamide compared to radiation or placebo. Moreover, the duration of response was shorter in the flutamide group than in the radiation alone group.

In animal studies, flutamide demonstrates potent antiandrogenic effects. It exerts its antiandrogenic activity by competitively inhibiting androgens at the cellular level. These effects include the inhibition of androgen action and the removal of the source of androgen, e.g., castration. Elevations of serum prostate-specific antigen (PSA) levels are decreased in most patients with hormone refractory prostate cancer treated with flutamide. Clinically significant reductions in PSA, testosterone, and dihydrotestosterone (DHT) levels were not observed in all clinical studies, however. PSA levels were decreased in 73% of patients with serum PSA values of 100 ng/mL or greater.

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C01C010

C01T3C03

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How should I take flutamide capsules?
Take your flutamide capsules as your doctor has prescribed. The usual dosing is 2 capsules every 8 hours. Your doctor will determine whether flutamide therapy is right for you based on many different factors. These include how large your tumor is, how far it has spread and your physical condition. In addition to flutamide capsules, you may be getting other treatments, including regular injections of LHRH agonist or radiation therapy. Do not stop or interrupt any treatment without consulting your healthcare professional.

If you miss a dose of flutamide capsules, simply continue therapy with your next scheduled dose. Do not try to make up for it by taking extra capsules.

Can I take other medicines?
If you are taking any other medicines, especially warfarin (a blood-thinning drug), tell your doctor before beginning flutamide therapy.

Are there any other side effects of taking flutamide capsules?
In a medical study, when flutamide capsules were taken together with an LHRH agonist, the most common side effects were hot flashes, loss of Sex drive (libido) and impotence. In addition, some men had diarrhea, nausea or vomiting, and breast enlargement.

In another medical study, when the flutamide product was taken together with goserelin acetate (an LHRH agonist) and radiation therapy, the side effects of flutamide therapy were about the same as when radiation therapy was given alone. These included hot flashes, diarrhea, nausea and skin rash.

What can I do if I get diarrhea?
If you experience moderate diarrhea due to flutamide capsules, the following advice may help:
- Drink plenty of fluids
- Reduce your intake of dairy products (for example, milk, cheese, yogurt)
- Increase your intake of whole grains, fruits and vegetables
- Avoid buttermilk
- Take nonprescription antidiarrheal medicines.

If your diarrhea continues or it becomes severe, contact your doctor right away.

Are there any other lab tests my doctor will be performing?
Your doctor may perform other regular tests (such as the PSA blood test) to ensure that your body is responding to treatment. Ask your doctor if you have any questions about how your flutamide therapy is being monitored.

Please ask your doctor about any questions concerning prostate cancer or flutamide therapy, or you can also ask for a more detailed leaflet that is written for healthcare professionals.

Manufactured by:
PAR PHARMACEUTICAL
Chestnut Ridge, NY 10977

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